Enforcement Report - Week of September 24, 2025

Class I Drugs Event

Event ID:
97482

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Unichem Pharmaceuticals USA Inc.
1 Tower Center Blvd Ste 2200
East Brunswick, NJ 08816-1145
United States

Distribution Pattern:
Nationwide within the U.S.A

Associated Products

Product Description:
Cyclobenzaprine Hydrochloride Tablets, USP, 10 mg, 90-count bottle, RX only, Manufactured by: Unichem Laboratories, Ltd, Pilerne Ind. Estate, Pilerne, Bardez, Goa, India; Manufactured for: Unichem Pharmaceuticals (USA), Inc. East Brunswick, NJ. NDC 29300-415-19.

Product Quantity:
230 90-count bottles

Reason for Recall:
Labeling: Label Mix Up; Bottles of Meloxicam USP, 7.5mg, 90-count tablets (yellow in color), were labeled as Cyclobenzaprine Hydrochloride Tablets USP, 10 mg 90-count tablets (blue in color).

Recall Number:
D-0655-2025

Code Information:
Lot No: GMML24026A, Expires: 09/30/2027

Class II Drugs Event

Event ID:
97460

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/03/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Kit for the Preparation of Technetium Tc 99m Mertiatide, Rx Only, Manufactured by: Sun Pharmaceutical Industries, Inc. Billerica, MA 01821, NDC 45567-0655-1

Product Quantity:
1870 kits

Reason for Recall:
Failed Dissolution Specifications-Out of Specification (OOS) observation for sulphate in Sodium Tartrate Dihydrate used for the production of Mertiatide.

Recall Number:
D-0658-2025

Code Information:
Lot# AD70995; Exp 10/31/2025

Class II Drugs Event

Event ID:
97477

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/26/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/16/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B BRAUN MEDICAL INC
861 Marcon Blvd
Allentown, PA 18109-9577
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
STERILE WATER FOR INJECTION USP, 3000mL, Rx only, B. Braun Medical Inc., Bethlehem. PA 18018, NDC 0264-7385-60.

Product Quantity:
26,316 3000 mL bags

Reason for Recall:
Lack of Assurance of Sterility- Potential for fluid leakage from the port due to port misalignment.

Recall Number:
D-0652-2025

Code Information:
Lot #: J3L519, J3L528, Exp.: 31AUG2026 Lot #: J4C522, J4C523, Exp.:28FEB2027

Product Description:
0.9% SODIUM CHLORIDE IRRIGATION USP. ISOTONIC SOLUTION FOR IRRIGATION, 3000mL, Rx only, B. Braun Medical Inc., Bethlehem, PA, 18018, USA, NDC 0264-7388-60.

Product Quantity:
16,228 3000 mL bags

Reason for Recall:
Lack of Assurance of Sterility- Potential for fluid leakage from the port due to port misalignment.

Recall Number:
D-0653-2025

Code Information:
Lot#: : J4C521, J4C516, J4C524, Exp. : 28FEB2027.

Class II Drugs Event

Event ID:
97511

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
135 Us Highway 202 206 Ste 15
Bedminster, NJ 07921-2608
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Aripiprazole Tablets, USP, 10 mg, 30-count bottles, Rx only, Manufactured by: Alken Laboratories Ltd., INDIA; Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054. NDC: 67877-432-03

Product Quantity:
2,256 bottles

Reason for Recall:
Superpotent drug

Recall Number:
D-0645-2025

Code Information:
Lot #: 24144162, Exp. Date 09/2027

Class II Drugs Event

Event ID:
97533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/15/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 25 mg, packaged as a) 50 (5x10) blisterpacks, NDC: 60687-430-65; (Individual Dose NDC: 60687-430-11); b) 100 (10x10) blisterpacks, NDC: 60687-430-01, (Individual Dose NDC: 60687-430-11), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217.

Product Quantity:
2,708 cartons

Reason for Recall:
Presence of a foreign substance.A specific lot of auxiliary polyester coil, used in product packaging at the manufacturing site, was detected with presence of a micro-organism. No micro-organism was detected on any tablets.

Recall Number:
D-0647-2025

Code Information:
Lot: a)1020919, 1021133, Exp 09/30/2026; 1021447, Exp 10/31/2026; 1021741, 1022202, Exp 11/30/2026; 1022474, Exp 12/31/2026 Lot: b) 1020460, exp 08/31/2026; 1022417, exp 12/31/2026

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 50 mg, 100 (10x10) blisterpacks, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. 50 Tablet Carton NDC#: 60687-441-01 (Individual Dose NDC: 60687-441-11)

Product Quantity:
1,062 cartons

Reason for Recall:
Presence of a foreign substance.A specific lot of auxiliary polyester coil, used in product packaging at the manufacturing site, was detected with presence of a micro-organism. No micro-organism was detected on any tablets.

Recall Number:
D-0648-2025

Code Information:
Lot: 1022159, exp 12/31/2026; 1023299, exp 03/31/2027; 1024057, Exp 04/30/2027

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 100 mg, 100 (10x10) blisterpack per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC#: 60687-452-01 (Individual unit dose blister pack NDC: 60687-452-11)

Product Quantity:
1,757 cartons

Reason for Recall:
Presence of a foreign substance.A specific lot of auxiliary polyester coil, used in product packaging at the manufacturing site, was detected with presence of a micro-organism. No micro-organism was detected on any tablets.

Recall Number:
D-0649-2025

Code Information:
Lot: 1021652, Exp 10/31/2026; 1022539, Exp 01/31/2027; 1023666, Exp 03/31/2027

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 200 mg, 100 (10x10) blisterpack per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC#: 60687-463-01 (Individual Dose NDC: 60687-463-11)

Product Quantity:
873 cartons

Reason for Recall:
Presence of a foreign substance.A specific lot of auxiliary polyester coil, used in product packaging at the manufacturing site, was detected with presence of a micro-organism. No micro-organism was detected on any tablets.

Recall Number:

D-0650-2025

Code Information:
Lot: 1021640, Exp 10/31/2026; 1022639, Exp 01/31/2027

Class II Drugs Event

Event ID:
97540

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron Compounding Services
8710 E 34th St N
Wichita, KS 67226-2636
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
bevacizumab (Avastin) Injection, 1.25mg/0.05mL (0.12 mL Fill), Sterile Single-Dose Syringe, Fagron Sterile Services, 8710 E 34th St N. Wichita, KS 67226

Product Quantity:
109,320 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0646-2025

Code Information:
Lot #: C274-000044756, C274-000044757, Exp 8-30-2025; C274-000044832, C274-000044833, Exp 9-4-2025; C274-000044882, C274-000044883, Exp 9-6-2025, C274-000044972, Exp 9-8-2025; C274-000045004, C274-000045005, Exp 9-18-2025 C274-000045108, exp. date 9-13-2025 C274-000045109, exp. date 9-13-2025 C274-000045136, exp. date 9-14-2025 C274-000045137, exp. date 9-14-2025 C274-000045289, exp. date 9-20-2025 C274-000045290, exp. date 9-20-2025 C274-000045350, exp. date 9-22-2025 C274-000045351, exp. date 9-22-2025 C274-000045387, exp. date 9-25-2025 C274-000045388, exp. date 9-25-2025 C274-000045516, exp. date 9-27-2025 C274-000045517, exp. date 9-27-2025 C274-000045586, exp. date 10-2-2025 C274-000045587, exp. date 10-2-2025 C274-000045676, exp. date 10-4-2025 C274-000045677, exp. date 10-4-2025 C274-000045707, exp. date 10-5-2025 C274-000045708, exp. date 10-5-2025 C274-000045754, exp. date 10-9-2025 C274-000045755, exp. date 10-9-2025 C274-000045840, exp. date 10-11-2025 C274-000045841, exp. date 10-11-2025 C274-000046048, exp. date 10-24-2025 C274-000046049, exp. date 10-24-2025 C274-000046095, exp. date 10-25-2025 C274-000046096, exp. date 10-25-2025 C274-000046122, exp. date 10-26-2025 C274-000046123, exp. date 10-26-2025 C274-000046164, exp. date 10-30-2025 C274-000046165, exp. date 10-30-2025 C274-000046191, exp. date 10-31-2025 C274-000046192, exp. date 10-31-2025 C274-000046240, exp. date 11-1-2025 C274-000046241, exp. date 11-1-2025 C274-000046315, exp. date 11-6-2025 C274-000046316, exp. date 11-6-2025 C274-000046345, exp. date 11-7-2025 C274-000046346, exp. date 11-7-2025 C274-000046515, exp. date 11-14-2025 C274-000046516, exp. date 11-14-2025 C274-000046603, exp. date 11-16-2025 C274-000046657, exp. date 11-20-2025 C274-000047136, exp. date 12-12-2025

Class II Drugs Event

Event ID:
97544

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Northwind Pharmaceuticals LLC
4838 Fletcher Ave Ste 1000
Indianapolis, IN 46203-1642
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Tablets, USP 800mg / 160mg Double Strength packaged in a) 6-count bottles (NDC 51655-307-87), b) 10-count bottles (NDC 51655-307-53), c) 14-count bottles (NDC 51655-307-84), d) 20-count bottles (NDC 51655-307-20) Rx Only, Repackaged from Amneal Pharmaceuticals LLC. Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46203.

Product Quantity:
a) 96 bottles, b) 627 bottles, c) 428 bottles, d) 1144 bottles

Reason for Recall:
Presence of a Foreign Substance: A specific lot of auxiliary polyester coil, used in product packaging by manufacturer (Amneal Pharmaceuticals LLC) was detected with presence of a micro-organism. No micro-organism was detected on any tablets.

Recall Number:
D-0654-2025

Code Information:
Lot #: a) F118062503, Exp Date 05/31/2027, F118062507, Exp Date. 07/31/2027. b) F118062504, F118062505, Exp. Date 05/31/2027; F118062509, Exp. Date. 08/31/2027; F118062512, Exp. Date 04/30/2027. c) F118062506, Exp. Date 06/30/2027. d) F118062423, Exp. Date 01/31/2027; F118062501, Exp. Date 06/30/2027; F118062502, Exp. Date 04/30/2027; F118062508, Exp. Date 08/31/2027.

Class II Drugs Event

Event ID:
97549

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/15/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton, NJ 08540-6604
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Cyclophosphamide Injection 500 mg/5 mL (100 mg/mL), Hazardous Drug, Rx Only, Sterile, 5mL Multiple Dose Vial, Manufactured in Austria by Fareva Unterach GmbH for Sandoz Inc., Princeton, NJ 08540, Product of India, Vial NDC# 0781-3528-75, Carton NDC# 0781-3528-10.

Product Quantity:
263 vials

Reason for Recall:
cGMP deviations: Temperature excursion during transportation.

Recall Number:
D-0651-2025

Code Information:
Lot # 110459 exp. date 02/28/2027

Class II Drugs Event

Event ID:
97556

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/18/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Entecavir Tablets, USP, 0.5 mg, 30 Tablets, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-920-06.

Product Quantity:
4344 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0656-2025

Code Information:
Lot E309376; Exp 11/30/2025

Product Description:
Entecavir Tablets, USP, 1 mg, 30 Tablets, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-921-06.

Product Quantity:
4440 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0657-2025

Code Information:
Lot E309377, Exp 11/30/2025